

# Agenda Item XI

## LEGISLATION AND REGULATION COMMITTEE REPORT



**California State Board of Pharmacy**

1625 N. Market Blvd, Suite N 219, Sacramento, CA 95834  
Phone (916) 574-7900  
Fax (916) 574-8618  
www.pharmacy.ca.gov

STATE AND CONSUMERS SERVICES AGENCY  
DEPARTMENT OF CONSUMER AFFAIRS  
GOVERNOR EDMUND G. BROWN, JR.

**Legislation and Regulation Committee**

**Shirley Wheat, Chair, Public Member**  
**Ramón Castellblanch, Public Member**  
**Deborah Veale, RPh**  
**Tappan Zee, Public Member**

**LEGISLATION AND REGULATION COMMITTEE REPORT**

*Summary of the Meeting Held April 24, 2012*

**PART I REGULATIONS**

**a. Board Approved - Undergoing Review by the Administration**

**ATTACHMENT 1**

- a. Add Title 16 Section 1727.2 – Requirements for Pharmacist Interns – To Require Applicants to Submit a Self-Query from the National Practitioner Data Bank – Healthcare Integrity & Protection Data Bank (NPDB-HIPDB)
- b. Amend Title 16 Section 1728 – Requirements for Pharmacist Examination – Amend to Require Applicants to Submit a Self-Query from the National Practitioner Data Bank – Healthcare Integrity & Protection Data Bank (NPDB-HIPDB)

On May 6, 2011, the board initiated a rulemaking to add Title 16 CCR § 1727.2 and to amend Title 16 CCR § 1728. The proposal would require a Pharmacist Intern applicant to submit with his or her application a Self-Query Report from the National Practitioner Data Bank – Healthcare Integrity & Protection Data Bank (NPDB-HIPDB). This proposal would also require an applicant seeking board authority to take the pharmacist licensure examination to submit with his or her application a Self-Query Report from the NPDB-HIPDB. The board determined that the requirement(s) to submit a Self-Query Report, as specified in the proposal, is necessary and pertinent to the board's investigation of an applicant and will allow the board to determine if an applicant has been the subject of discipline in another state prior to making a decision on an application. This is the same type of Self-Query Report that was recently approved in 2011 for Pharmacy Technician applicants.

The board did not receive any comments during the 45-day comment period and in July 2011 the board directed staff to complete the rulemaking process. The Executive Officer adopted the text as proposed in the Notice for the 45-day public comment

period. Staff compiled the final rulemaking file and submitted it to the Department of Consumer Affairs for administrative review on November 10, 2011.

Board staff has been advised that the DCA and the State and Consumer Services Agency have completed their review. The file has been at the Department of Finance awaiting review / approval since January 9, 2012, but as of April 25, 2012, the Department of Finance had not completed its review. Once all administrative approvals are received, the board will file the rulemaking with the Office of Administrative Law for final approval

The one-year notice period for this rulemaking will expire on May 5, 2012, unless extended by the Director of the Department of Consumer Affairs. A copy of the Adopted Text is provided in **Attachment 1**.

## **b. Discussion and Possible Action – Board Approved Regulations Noticed**

### **ATTACHMENT 2**

1. Proposed Amendments to Title 16 California Code of Regulations Section 1760 – Board of Pharmacy *Disciplinary Guidelines*, Including to Incorporate Recommendations of the Substance Abuse Coordination Committee (Pursuant to SB 1441, Ridley-Thomas, Chapter 548, Statutes of 2008)  
*[45-day comment period: October 24-November 8, 2011]*

#### Relevant Sections

California Code of Regulations Section 1760 requires the board to consider disciplinary guidelines when reaching a decision on a disciplinary action.

Business and Professions Code Section 315 established the Substance Abuse Coordination Committee (SACC) within the Department of Consumer Affairs. The committee was charged with formulating uniform and specific standards in several areas for dealing with substance-abusing licensees.

Chapter 9, Division 2, Chapter 19 (business and professions code sections 4300-4315) defines disciplinary proceeding for the board as well as the grounds for taking such discipline.

#### Background

Last year the board directed staff to a restructuring and updating of its Disciplinary Guidelines last year. Subsequent to this, in April 2011, the SACC finalized the uniform standards required in B&PC section 315. Many of these standards need to be incorporated into the guidelines as well to facilitate implementation.

During the July 2011 Board meeting, staff was directed to incorporate the uniform standards into the disciplinary guidelines for consideration by the board at a future meeting. Most Recently, during the September 2011 Board Meeting, the board voted to

initiate a rulemaking to amend Section 1760 and the Disciplinary Guidelines that are incorporated by reference in this section.

On October 14, 2012, the board released the rulemaking, initiating the 45-day comment period on the proposed changes. In addition to releasing this for a 45-day comment period, the board, as part of its notice, held a regulation hearing during the January 2012 Board Meeting.

During the January 2012 Board Meeting, the board discussed the proposed change and the comments received in response to the rulemaking consistent with the administrative procedures process established in the government code. At the conclusion of this discussion the board voted to make several changes to the proposed language and requested that the proposed changes be brought back to the board prior to staff releasing the changes as part of a 15-day comment. Specifically the board requested the following changes.

- Modify term 24 of the proposed amendments to the Disciplinary Guidelines to strike the testing frequency and replace with more general language consistent with the board's discussion and to strike the section regarding specimen collectors.
- Modify term 30 to strike all language regarding the minimum requirements for facilitators or evaluators within the proposed language.

#### Recent Update

Prior to staff preparing the changes for consideration, staff received correspondence from the DCA legal office regarding SB 1441 implementation. This information was shared with the executive staff and clarifications regarding the department's expectations and future actions were provided in later meetings with the legal office in late April. As the department's recently expressed expectation does not fully support the action taken by the board during its January 2012 meeting, staff needs to refer this matter back to the board for discussion and possible further action.

**Attachment 2** contains a copy of the Memo from Doreatha Johnson, Deputy Director of Legal Affairs, DCA as well as a copy of a legal opinion issued from the Legislative Counsel Bureau and an executive summary issued by the Office of the Attorney General.

Staff and counsel will be prepared to discuss this issue in more detail.

2. Proposed Amendments to Title 16, Section 1746 – Emergency Contraception Protocol Review and Discussion of Comments Submitted During 45-day Comment Period  
[45-day comment period: January 6 – February 20, 2012]

### **ATTACHMENT 3**

At this meeting, the board will consider the comments received during the 45-day public comment period. In addition, the women's health specialist for the California Pharmacists Association will be available to answer the board's questions.

In October 2011, the board voted to initiate a proposed rulemaking to update the board's Emergency Contraception Protocol at Title 16 Section 1746, to reflect the language and protocol approved by the Medical Board of California in July 2011.

The board noticed the proposed regulation on January 6, 2012, and the 45-day public comment period concluded on February 20, 2012. The board received one comment during that period, which is attached.

Business and Professions Code Section 4052.3 authorizes a pharmacist to initiate emergency contraception therapy in accordance with either (1) standardized procedures or protocols developed by the pharmacist and an authorized prescriber, as specified; and (2) standardized procedures or protocols developed and approved by both the Medical Board of California and the Board of Pharmacy, as specified.

The current state protocol was developed by the Medical Board in 2004 and was adopted by the Board of Pharmacy that same year. Title 16 CCR § 1746 became operative on December 2, 2004. Since that time, there have been changes in the availability of emergency contraception medicine, the manufacturers who produce the medication. The protocol also has a typographical error that requires correction (mcg instead of mg).

Following the adoption of a new emergency contraception protocol, the board will then need to update its patient information fact sheet. This fact sheet is required by Section 4052.3(e) of the Business and Professions Code and is provided to the patient by the pharmacist using the protocol to dispense emergency contraception. The update of a fact sheet would be vetted through the board's Communication and Public Education Committee.

A copy of the proposed text and comments received are provided in **Attachment 3**.

### **c. Discussion and Possible Action – Board Approved Regulations**

#### **ATTACHMENT 4**

##### **1. Proposed Amendments to Section 1780 – Update the USP Standards Reference Manual (Minimum Standards for Drug Wholesalers)**

Section 1780 of the California Code of Regulations sets minimum standards for drug wholesalers. This regulation currently references the 1990 edition of the United States Pharmacopeia Standards (USP Standards) for temperature and humidity. USP Standards are updated and published annually. Section 1780(b) requires amendment to reflect the 2005 version of the USP Standards and to hold wholesalers accountable to the latest standards, if determined appropriate.

Because of stated concerns about whether referencing the 2005 USP Standards would be an unreasonable burden on wholesalers, at the October 2008 Board Meeting, the board voted to address the issue of updating the USP Standards reference materials within this section.

The board established a subcommittee for this purpose but, as a result of board vacancies, the subcommittee has not held any meetings and no action has been taken with respect to this regulation change.

2. Proposed Amendments to Section 1785 – Self-Assessment of a Veterinary Food-Animal Drug Retailer

The requirements of § 1785 establish a self-assessment form for veterinary food-animal drug retailers and requires a designated representative-in-charge to complete this form to ensure compliance with pharmacy law. Self-assessment forms also aid licensees in complying with legal requirements of their operations and, therefore, increase public safety as a result of this compliance.

In 2007 the Enforcement Committee and the Board approved draft amendments to the regulation and related self-assessment form; subsequently, the licensing committee was advised of potential problems with the licensing requirements for designated representatives working at these facilities.

The Licensing Committee has not yet initiated a program review of the Veterinary Food-Animal Drug Retailer program. Staff does not anticipate proceeding with this regulation until such time that the Licensing Committee completes its review.

3. Proposed Addition of Section 1762 – Unprofessional Conduct

In October 2010, the board began discussions to add 16 CCR § 1762 to implement components of the DCA's Consumer Protection Enforcement Initiative relative to unprofessional conduct. In February 2011 the board addressed draft language and moved to initiate the rulemaking process to amend Section 1762 to specify that certain acts would constitute unprofessional conduct including: gag clauses in a civil suit settlement; failure to provide information as requested by the board; failure to comply with a court order or subpoena for records; and authorize the board to revoke a license or deny an application for an act requiring an individual to register as a sex offender.

Staff is working to prepare a rulemaking package for a 45-day public comment period. **Attachment 4** includes a copy of the proposed text approved by the board.

4. Proposed Addition of Section 1769 – Application Review and Criteria for Rehabilitation

Protection Enforcement Initiative with regarding to 16 CCR § 1769 – a proposal that would authorize the board to request that an applicant for licensure undergo an examination, as specified, to determine if the applicant is safe to practice. The board directed that staff initiate the rulemaking process to amend 16 CCR § 1769, specifying that once it has been determined that an applicant is to be evaluated, the evaluation shall be completed within 60 days, and that within 60 days of the evaluation, the report be received by the board.

Staff is working to prepare a rulemaking package for a 45-day public comment period. **Attachment 4** includes a copy of the proposed text approved by the board.

5. Proposed Amendment of Title 16 Section 1745 – Partial Fill of Schedule II Controlled Substance

At the October 2010 Board Meeting the board voted to initiate a rulemaking to amend Section 1745(c)(2) to allow pharmacies to maintain electronic records or document on the original prescription when partially filling a Schedule II controlled substance. The language approved by the board is below. Staff is working to prepare a rulemaking package for a 45-day public comment period.

1745(c)(2) The pharmacist records the date and amount of each partial filling in a readily retrievable form ~~and~~ or on the original prescription, also recording the initials of the pharmacist dispensing the prescription;

6. Proposed Amendments to Section 1751.2 and 1751.9 – Sterile Injectable Compounding, Sterile Injectable Labeling Requirements, and Accreditation Agencies

The board voted to amend Section 1751.2 related to the labeling of cytotoxic agents at its Board Meeting held January 31, 2012. The proposed amendments were included in the board's noticed rulemaking to also amend Title 16 Sections 1735.1, 1735.2, and 1735.3 (see Agenda Item X. for additional information on this rulemaking).

The board's proposal related to Section 1751.9 has been referred to the Licensing Committee, and will be brought back to the board for future consideration.

7. Proposed Amendments to Section 1780 – Minimum Standards for Wholesalers

Section 1780 of the California Code of Regulations sets minimum standards for drug wholesalers. This regulation currently references the 1990 edition of the United States Pharmacopeia Standards (USP Standards) for temperature and humidity. USP Standards are updated and published annually. Section 1780(b) requires amendment to reflect the 2005 version of the USP Standards and to hold wholesalers accountable to the latest standards, if determined appropriate.

Because of stated concerns about whether referencing the 2005 USP Standards would be an unreasonable burden on wholesalers, at the October 2008 Board Meeting, the board voted to address the issue of updating the USP Standards reference materials within this section.

The board established a subcommittee for this purpose but, as a result of board vacancies, the subcommittee has not held any meetings and no action has been taken with respect to this regulation change.

8. Proposed Amendments to Section 1732.2 – Board Accredited Continuing Education

At the Board Meeting held January 31, 2012, the board considered amendments to the board's continuing education regulation. At that time, a rulemaking to amend Section 1732.2 related to continuing education was pending final review at the Office of Administrative Law. The board voted to withdraw from OAL its rulemaking to amend Title 16 of the California Code of Regulations Section 1732.2 and refer the matter to the Licensing Committee for further review.



# Attachment 1

**Order of Adoption  
Board of Pharmacy  
California Code of Regulations**

**Add Section 1727.2. to Article 3 of Division 17 of Title 16 of the California Code of Regulations to read as follows:**

**§ 1727.2. Requirements for Pharmacist Intern.**

Every applicant for a pharmacist intern license shall submit as part of the application process, a sealed, original Self Query Report from the National Practitioner Data Bank – Healthcare Integrity and Protection Data Bank (NPDB-HIPDB), dated no earlier than 60 days before the date an application is submitted to the board.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4207 and 4208, Business and Professions Code.

**Amend Section 1728. in Article 3 of Division 17 of Title 16 of the California Code of Regulations to read as follows:**

**§ 1728. Requirements for Examination.**

(a) Prior to receiving authorization from the board to take the pharmacist licensure examinations required by section 4200 of the Business and Professions Code, applicants shall submit to the board the following:

(1) Proof of 1500 hours of pharmacy practice experience that meets the following requirements:

(A) A minimum of 900 hours of pharmacy practice experience obtained in a pharmacy.

(B) A maximum of 600 hours of pharmacy practice experience may be granted at the discretion of the board for other experience substantially related to the practice of pharmacy.

(C) Experience in both community pharmacy and institutional pharmacy practice settings.

(D) Pharmacy practice experience that satisfies the requirements for both introductory and advanced pharmacy practice experiences established by the Accreditation Council for Pharmacy Education.

(2) Satisfactory proof that the applicant graduated from a recognized school of pharmacy.

(3) Fingerprints to obtain criminal history information from both the Department of Justice and the United States Federal Bureau of Investigation pursuant to Business and Professions Code section 144.

(4) A signed copy of the examination security acknowledgment.

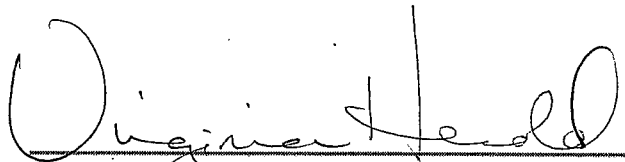
(5) A sealed, original Self Query Report from the National Practitioner Data Bank – Healthcare Integrity and Protection Data Bank (NPDB-HIPDB), dated no earlier than 60 days before the date an application for examination as a pharmacist is submitted to the board.

(b) Applicants who hold or held a pharmacist license in another state shall provide a current license verification from each state in which the applicant holds or held a pharmacist license prior to being authorized by the board to take the examinations.

(c) Applicants who graduated from a foreign school of pharmacy shall provide the board with satisfactory proof of certification by the Foreign Pharmacy Graduate Examination Committee prior to being authorized by the board to take the examinations.

Note: Authority cited: Sections 851 and 4005, Business and Professions Code.

Reference: Sections 144, 851 and 4200, Business and Professions Code.

A handwritten signature in black ink, appearing to read "Virginia Herold", written over a horizontal line.


Virginia Herold  
Executive Officer  
Board of Pharmacy

# Attachment 2



2012 APR -5 PM 3:08

## MEMORANDUM

<b>DATE</b>	<b>April 5, 2012</b>
<b>TO</b>	<b>ALL HEALING ARTS BOARDS</b>
<b>FROM</b>	 <b>DOREATHEA JOHNSON</b> <b>Deputy Director, Legal Affairs</b> <b>Department of Consumer Affairs</b>
<b>SUBJECT</b>	<b>Opinion Regarding Uniform Standards for Substance-Abusing Licensees (SB 1441)</b>

This memo addresses a number of questions that have been raised concerning the discretion of healing arts boards, with respect to the Uniform Standards for Substance-Abusing Healing Arts Licensees ("Uniform Standards") that were formulated by the Substance Abuse Coordination Committee and mandated by Business and Professions Code section 315. Previously, there have been discussions and advice rendered, opining that the boards retain the discretion to modify the Uniform Standards. This opinion, largely influenced by the fact that the rulemaking process necessarily involves the exercise of a board's discretion, has been followed by a number of boards as they completed the regulatory process.

Two opinions, one issued by the Legislative Counsel Bureau ("Legislative Counsel") dated October 27, 2011, and an informal legal opinion, rendered by the Government Law Section of the Office of the Attorney General ("Attorney General"), dated February 29, 2012, have been issued and address the discretion of the boards, in adopting the Uniform Standards. This memo is to advise the healing arts boards of this office's opinion regarding the questions raised, after a review of these two opinions. A copy of each opinion is attached for your convenience.

Questions Presented

1. **Do the healing arts boards retain the discretion to modify the content of the specific terms or conditions of probation that make up the Uniform Standards?**

*Both Legislative Counsel and the Attorney General concluded that the healing arts boards do not have the discretion to modify the content of the specific terms or conditions of probation that make up the Uniform Standards. We concur with that conclusion.*

2. **Do the healing arts boards have the discretion to determine which of the Uniform Standards apply in a particular case?**

*Legislative Counsel opined that, unless the Uniform Standards specifically so provide, all of the Uniform Standards must be applied to cases involving substance-abusing licensees, as it was their belief that the Legislative intent was to "provide for the full implementation of the Uniform Standards." The Attorney General agreed with Legislative Counsel. Following our review and analysis of Business and Professions Code Section 315, we concur with both the Office of the Attorney General and the Legislative Counsel.*

3. **Is the Substance Abuse Coordination Committee (SACC) the entity with rulemaking authority over the uniform standards to be used by the healing arts boards?**

*The Legislative Counsel concluded that the SACC had the authority to promulgate regulations mandating that the boards implement the Uniform Standards. However, the Office of the Attorney General disagreed and concluded that the SACC was not vested with the authority to adopt regulations implementing the uniform standards. We agree with the Office of the Attorney General. It is our opinion that the authority to promulgate the regulations necessary to implement the Uniform Standards, lies with the individual boards that implement, interpret or make specific, the laws administered by those boards. As the SACC is limited to the creation or formulation of the uniform standards, but is not authorized to implement the laws of the healing arts boards, it does not have authority to adopt regulations to implement those standards. Consequently, we agree with the Attorney General's opinion that the SACC is not the rule-making entity with respect to the Uniform Standards, and therefore has no authority to adopt the Uniform Standards as regulations.*

It is our recommendation that healing arts boards move forward as soon as possible to implement the mandate of Business and Professions Code section 315, as it relates to

the Uniform Standards. Some of the standards are appropriate for inclusion in an agency's disciplinary guidelines, which necessarily will involve the regulatory process. Others are administrative in nature and not appropriate for inclusion in the disciplinary guidelines. For example, Uniform Standard No. 16 which sets forth reporting requirements would not be appropriate for inclusion in disciplinary guidelines.

Please work with your assigned legal counsel to determine how best to implement the Uniform Standards. This should include a discussion as to whether : (1) the Uniform Standards should be placed in a regulation separate from the disciplinary guidelines; (2) the implementing regulation should include a definition of (or criteria by which to determine) what constitutes a "substance-abusing licensee."

It is hopeful that the foregoing information addresses your concerns with respect to the implementation of the mandatory uniform standards.

Attachments

cc: Denise Brown, DCA Director  
Awet Kidane, DCA Chief Deputy Director  
DCA Legal Affairs Attorneys





LEGISLATIVE  
COUNCIL  
BUREAU

LEGISLATIVE COUNCIL BUREAU

1500 S. STREET, SUITE 100

SAN FRANCISCO, CALIFORNIA 94109

TELEPHONE (415) 774-3100

FACSIMILE (415) 774-3101

WWW.LEGISLATIVECOUNCIL.BUREAU.CA.GOV

October 27, 2011

Honorable Curren D. Price Jr.  
Room 2053, State Capitol

HEALING ARTS BOARDS: ADOPTION OF UNIFORM STANDARDS - #1124437

Dear Senator Price:

You have asked two questions with regard to the adoption of uniform standards by the Substance Abuse Coordination Committee pursuant to Section 315 of the Business and Professions Code. You have asked whether the Substance Abuse Coordination Committee is required to adopt the uniform standards pursuant to the rulemaking procedures under the Administrative Procedure Act (Ch. 3.5 (commencing with Sec. 11340), Pt. 1, Div. 3, Title 2, Gov. C.). You have also asked, if the uniform standards are properly adopted by the Substance Abuse Coordination Committee, whether the healing arts boards are required to implement them.

By way of background, Section 315 of the Business and Professions Code<sup>1</sup> provides as follows:

"315. (a) For the purpose of determining uniform standards that will be used by healing arts boards in dealing with substance-abusing licensees, there is established in the Department of Consumer Affairs the Substance Abuse Coordination Committee. The committee shall be comprised of the executive officers of the department's healing arts boards established pursuant to Division 2 (commencing with Section 500), the State Board of Chiropractic Examiners, the Osteopathic Medical Board of California, and a designee of the State Department of Alcohol and Drug Programs. The Director of Consumer Affairs shall chair the committee and may invite individuals or stakeholders who have particular expertise in the area of substance abuse to advise the committee.

---

<sup>1</sup> All further section references are to the Business and Professions Code, unless otherwise referenced.

"(b) The committee shall be subject to the Bagley-Keene Open Meeting Act (Article 9 (commencing with Section 11120) of Division 3 of Title 2 of the Government Code).

"(c) By January 1, 2010, the committee shall formulate uniform and specific standards in each of the following areas that each healing arts board shall use in dealing with substance-abusing licensees, whether or not a board chooses to have a formal diversion program:

"(1) Specific requirements for a clinical diagnostic evaluation of the licensee, including, but not limited to, required qualifications for the providers evaluating the licensee.

"(2) Specific requirements for the temporary removal of the licensee from practice, in order to enable the licensee to undergo the clinical diagnostic evaluation described in paragraph (1) and any treatment recommended by the evaluator described in paragraph (1) and approved by the board, and specific criteria that the licensee must meet before being permitted to return to practice on a full-time or part-time basis.

"(3) Specific requirements that govern the ability of the licensing board to communicate with the licensee's employer about the licensee's status and condition.

"(4) Standards governing all aspects of required testing, including, but not limited to, frequency of testing, randomness, method of notice to the licensee, number of hours between the provision of notice and the test standards for specimen collectors, procedures used by specimen collectors, the permissible locations of testing, whether the collection process must be observed by the collector, backup testing requirements when the licensee is on vacation or otherwise unavailable for local testing, requirements for the laboratory that analyzes the specimens, and the required maximum timeframe from the test to the receipt of the result of the test.

"(5) Standards governing all aspects of group meeting attendance requirements, including, but not limited to, required qualifications for group meeting facilitators, frequency of required meeting attendance, and methods of documenting and reporting attendance or nonattendance by licensees.

"(6) Standards used in determining whether inpatient, outpatient, or other type of treatment is necessary.

"(7) Worksite monitoring requirements and standards, including, but not limited to, required qualifications of worksite monitors, required methods of monitoring by worksite monitors, and required reporting by worksite monitors.

"(8) Procedures to be followed when a licensee tests positive for a banned substance.

"(9) Procedures to be followed when a licensee is confirmed to have ingested a banned substance.

"(10) Specific consequences for major violations and minor violations. In particular, the committee shall consider the use of a deferred prosecution stipulation similar to the stipulation described in Section 1000 of the Penal Code, in which the licensee admits to self-abuse of drugs or alcohol and surrenders his or her license. That agreement is deferred by the agency unless or until the licensee commits a major violation, in which case it is revived and the license is surrendered.

"(11) Criteria that a licensee must meet in order to petition for return to practice on a full-time basis.

"(12) Criteria that a licensee must meet in order to petition for reinstatement of a full and unrestricted license.

"(13) If a board uses a private-sector vendor that provides diversion services, standards for immediate reporting by the vendor to the board of any and all noncompliance with any term of the diversion contract or probation; standards for the vendor's approval process for providers or contractors that provide diversion services, including, but not limited to, specimen collectors, group meeting facilitators, and worksite monitors; standards requiring the vendor to disapprove and discontinue the use of providers or contractors that fail to provide effective or timely diversion services; and standards for a licensee's termination from the program and referral to enforcement.

"(14) If a board uses a private-sector vendor that provides diversion services, the extent to which licensee participation in that program shall be kept confidential from the public.

"(15) If a board uses a private-sector vendor that provides diversion services, a schedule for external independent audits of the vendor's performance in adhering to the standards adopted by the committee.

"(16) Measurable criteria and standards to determine whether each board's method of dealing with substance-abusing licensees protects patients from harm and is effective in assisting its licensees in recovering from substance abuse in the long term." (Emphasis added.)

Thus, the Legislature has established in the Department of Consumer Affairs (hereafter department) the Substance Abuse Coordination Committee (subd. (a), Sec. 315, hereafter committee). The committee is comprised of the executive officers of each healing arts board within the department,<sup>2</sup> the State Board of Chiropractic Examiners, and the

---

<sup>2</sup> The department's healing arts boards are those boards established under Division 2 (commencing with Section 500) to license and regulate practitioners of the healing arts. Those boards include, among others, the Dental Board of California, the Medical Board of California, the Veterinary Medical Board, and the Board of Registered Nursing.

Osteopathic Medical Board of California (hereafter, collectively, healing arts boards), and a designee of the State Department of Alcohol and Drug Programs (Ibid.). The Director of Consumer Affairs chairs the committee and is authorized to invite individuals or stakeholders who have particular expertise in the area of substance abuse to advise the committee (Ibid.).

The committee is required to formulate uniform and specific standards in each of 16 areas provided by the Legislature, but otherwise has discretion to adopt the uniform standards each healing arts board shall use in dealing with substance-abusing licensees (subd. (c), Sec. 315). The committee adopted its initial set of uniform standards in April 2010, and revised those initial standards as recently as April 2011.<sup>3</sup> Although the committee has adopted the uniform standards pursuant to its own procedures, it has yet to adopt those standards pursuant to the rulemaking procedures of the Administrative Procedure Act (Ch. 3.5 (commencing with Sec. 11340), Pt. 1, Div. 3, Title 2, Gov. C.; hereafter APA).

You have asked whether the committee is required to adopt the uniform standards pursuant to the rulemaking procedures of the APA.

The APA establishes basic minimum procedural requirements for the adoption, amendment, or repeal of administrative regulations by state agencies (subd. (a), Sec. 11346, Gov. C.). The APA is applicable to the exercise of any quasi-legislative power conferred by any statute (Ibid.). Quasi-legislative powers consist of the authority to make rules and regulations having the force and effect of law (*California Advocates for Nursing Home Reform v. Bonta* (2003) 106 Cal.App.4th 498, 517; hereafter *California Advocates*). The APA may not be superseded or modified by any subsequent legislation except to the extent that the legislation does so expressly (subd. (a), Sec. 11346, Gov. C.).

The term "regulation" is defined for purposes of the APA to mean "every rule, regulation, order, or standard of general application or the amendment, supplement, or revision of any rule, regulation, order, or standard adopted by any state agency to implement, interpret, or make specific the law enforced or administered by it, or to govern its procedure" (Sec. 11342.600, Gov. C.; emphasis added). The APA provides that a state agency shall not issue, utilize, enforce, or attempt to enforce any guideline, criterion, bulletin, manual, instruction, order, standard of general application, or other rule, which is a regulation under the APA, unless properly adopted under the procedures set forth in the APA, and the Office of Administrative Law is empowered to determine whether any such guideline, criterion, bulletin, manual, instruction, order, standard of general application, or other rule is a regulation under the APA (Sec. 11340.5, Gov. C.).

In *Tidewater Marine Western, Inc. v. Bradshaw* (1996) 14 Cal.4th 557, 571 (hereafter *Tidewater*), the California Supreme Court found as follows:

---

<sup>3</sup> See [http://www.dca.ca.gov/about\\_dca/sacc/index.shtml](http://www.dca.ca.gov/about_dca/sacc/index.shtml) (as of September 20, 2011).

"A regulation subject to the APA thus has two principal identifying characteristics. (See *Union of American Physicians & Dentists v. Kizer* (1990) 223 Cal.App.3d 490, 497 [272 Cal.Rptr. 886] [describing two-part test of the Office of Administrative Law].) First, the agency must intend its rule to apply generally, rather than in a specific case. The rule need not, however, apply universally; a rule applies generally so long as it declares how a certain class of cases will be decided. (*Roth v. Department of Veterans Affairs* (1980) 110 Cal.App.3d 622, 630 [167 Cal.Rptr. 552].) Second, the rule must implement, interpret, or make specific the law enforced or administered by [the agency], or ... govern [the agency's] procedure." (Gov. Code, § 11342, subd. (g).)"

If a policy or procedure falls within the definition of a "regulation" within the meaning of the APA, the adopting agency must comply with the procedures for formalizing the regulation, which include public notice and approval by the Office of Administrative Law (*County of Butte v. Emergency Medical Services Authority* (2010) 187 Cal.App.4th 1175, 1200). The Office of Administrative Law is required to review all regulations adopted pursuant to the APA and to make its determinations according to specified standards that include, among other things, assessing the necessity for the regulation and the regulation's consistency with the agency's statutory obligation to implement a statute (subd. (a), Sec. 11349.1, Gov. C.).

Applying these principles to the question presented, the uniform standards are subject to the rulemaking procedures of the APA if the following criteria are met: (1) Section 315 does not expressly preclude application of the APA, (2) the committee is a state agency under the APA, (3) the uniform standards are regulations subject to the APA, and (4) no exemption applies under the APA.

With respect to the first criterion, Section 315 is silent on the application of the APA. Thus, Section 315 does not expressly preclude application of the APA, and the APA will apply to any regulation adopted under Section 315.

We turn next to the second criterion, and whether the committee is an "agency" for purposes of the APA. The word "agency" is defined, for purposes of the APA, by several separate provisions of law. For purposes of the rulemaking procedures of the APA, "agency" is defined to mean a state agency (Sec. 11342.520, Gov. C.). That reference to state agency is defined elsewhere in the Government Code to include every state office, officer, department, division, bureau, board, and commission (subd. (a), Sec. 11000, Gov. C.). The APA does not apply to an agency in the judicial or legislative branch of the state government (subd. (a), Sec. 11340.9, Gov. C.).

Along those lines, the APA is applicable to the exercise of any quasi-legislative power conferred by any statute (subd. (a), Sec. 11346, Gov. C.). Quasi-legislative powers consist of the authority to make rules and regulations having the force and effect of law (*California Advocates*, supra, at p. 517). Thus, for purposes of our analysis, we think that an "agency" means any state office, officer, department, division, bureau, board, or commission that exercises quasi-legislative powers.

Here, the committee is a state office comprised of executive officers of the healing arts boards and the Director of Consumer Affairs. Although the Legislature has set forth 16 areas in which the committee is required to adopt standards, the committee itself is required to exercise quasi-legislative powers and adopt uniform standards within those areas. Those standards shall have the force and effect of law, since the healing arts boards, as discussed more extensively below, are required to use the standards in dealing with substance-abusing licensees and the standards are required to govern matters such as when a licensee is temporarily removed from practice or subject to drug testing or work monitoring (paras. (2), (4), and (7), subd. (c), Sec. 315). Accordingly, we think the committee is an agency to which the APA applies.

As to the third criterion, two elements must be met for the uniform standards at issue to be a regulation: they must apply generally and they must implement, interpret, or make specific a law enforced or administered by the agency or that governs its procedures (*Tidewater*, supra, at p. 571; Sec. 11342.600, Gov. C.). Section 315 requires the committee to formulate uniform and specific standards in specified areas that each healing arts board within the department shall use when dealing with substance-abusing licensees, whether or not the board chooses to have a formal diversion program. The uniform standards will not be limited in application to particular instances or individuals but, instead, will apply generally to those licensees. Further, under this statutory scheme, the uniform standards will implement Section 315 and will be enforced and administered by, and will govern the procedures of, each healing arts board that is a member of the committee. Thus, the uniform standards are, in our view, a regulation under the APA.

Lastly, we turn to the fourth criterion, and whether the regulation is exempt from the APA. Certain policies and procedures are expressly exempted by statute from the requirement that they be adopted as regulations pursuant to the APA. In that regard, Section 11340.9 of the Government Code provides as follows:

"11340.9. This chapter does not apply to any of the following:

"(a) An agency in the judicial or legislative branch of the state government.

"(b) A legal ruling of counsel issued by the Franchise Tax Board or State Board of Equalization.

"(c) A form prescribed by a state agency or any instructions relating to the use of the form, but this provision is not a limitation on any requirement that a regulation be adopted pursuant to this chapter when one is needed to implement the law under which the form is issued.

"(d) A regulation that relates only to the internal management of the state agency.

"(e) A regulation that establishes criteria or guidelines to be used by the staff of an agency in performing an audit, investigation, examination, or inspection, settling a commercial dispute, negotiating a commercial

arrangement, or in the defense, prosecution, or settlement of a case, if disclosure of the criteria or guidelines would do any of the following:

- "(1) Enable a law violator to avoid detection.
- "(2) Facilitate disregard of requirements imposed by law.
- "(3) Give clearly improper advantage to a person who is in an adverse position to the state.
- "(f) A regulation that embodies the only legally tenable interpretation of a provision of law.
- "(g) A regulation that establishes or fixes rates, prices, or tariffs.
- "(h) A regulation that relates to the use of public works, including streets and highways, when the effect of the regulation is indicated to the public by means of signs or signals or when the regulation determines uniform standards and specifications for official traffic control devices pursuant to Section 21400 of the Vehicle Code.
- "(i) A regulation that is directed to a specifically named person or to a group of persons and does not apply generally throughout the state."

None of the exemptions contained in the APA can be reasonably construed to apply to the committee or the uniform standards to be used by the healing arts boards. In addition, we are aware of no other applicable exemption.

Thus, because all four of the criteria are met, it is our opinion that the Substance Abuse Coordination Committee is required to adopt the uniform standards pursuant to the rulemaking procedures under the Administrative Procedure Act (Ch. 3.5 (commencing with Sec. 11340), Pt. 1, Div. 3, Title 2, Gov. C.).

Having reached this conclusion, we next turn to whether the healing arts boards are required to use the uniform standards if those standards are properly adopted. In addressing that question, we apply certain established rules of statutory construction. To ascertain the meaning of a statute, we begin with the language in which the statute is framed (*Leroy T. v. Workmen's Comp. Appeals Bd.* (1974) 12 Cal.3d 434, 438; *Visalia School Dist. v. Workers' Comp. Appeals Bd.* (1995) 40 Cal.App.4th 1211, 1220). Significance should be given to every word, and construction making some words surplusage is to be avoided (*Lambert Steel Co. v. Heller Financial, Inc.* (1993) 16 Cal.App.4th 1034, 1040). In addition, effect should be given to statutes according to the usual, ordinary import of the language employed in framing them (*DuBais v. Workers' Comp. Appeals Bd.* (1993) 5 Cal.4th 382, 388).

As set forth above, subdivision (c) of Section 315 provides that "the committee shall formulate uniform and specific standards in each of the following areas that each healing arts board shall use in dealing with substance-abusing licensees, whether or not a board chooses to have a formal diversion program" (emphasis added). Section 19 provides that "shall" is mandatory and "may" is permissive. The word "may" is ordinarily construed as permissive, whereas the word "shall" is ordinarily construed as mandatory (*Common Cause v. Board of Supervisors* (1989) 49 Cal.3d 432, 443).

Here, in Section 315, the Legislature uses the term "shall" rather than "may" in providing that each healing arts board "shall use" the specific and uniform standards adopted by the committee when dealing with substance-abusing licensees. The Legislature uses the term "shall use" as compared to "shall consider," "may consider," or "may use." The Legislature's use of the term "shall" indicates that the healing arts boards are required to use the standards adopted by the committee rather than being provided the discretion to do so. Moreover, as employed in this context, the word "use" implies that the healing arts boards must implement and apply those standards rather than merely considering them. Finally, the use of the term "uniform" suggests that the Legislature intended each board to apply the same standards. If the healing arts boards were not required to use the standards as adopted by the committee, the standards employed by these boards would vary rather than being "uniform."

Norwithstanding the plain meaning of Section 315, one could argue that the enactment of Section 315.4 indicates that the Legislature intended that implementation of the uniform standards by the boards be discretionary. Section 315.4, which was added by Senate Bill No. 1172, of the 2009-10 Regular Session (Ch. 517, Stats. 2010; hereafter S.B. 1172), provides that a healing arts board "may adopt regulations authorizing the board to order a licensee on probation or in a diversion program to cease practice for major violations and when the board orders a licensee to undergo a clinical diagnostic evaluation pursuant to the uniform and specific standards adopted and authorized under Section 315." Section 315.4 could be read to imply that a healing arts board is not required to implement those uniform standards because the board was given discretion to adopt the regulations that would allow that board to implement the standards, if necessary.

It is a maxim of statutory construction that a statute is to be construed so as to harmonize its various parts within the legislative purpose of the statute as a whole (*Wells v. Marina City Properties, Inc.* (1981) 29 Cal.3d 781, 788). As discussed above, we believe that the plain meaning of Section 315 requires the healing arts boards to implement the uniform standards adopted by the committee. Thus, whether Section 315.4 indicates, to the contrary, that the Legislature intended the boards to have discretion in that regard depends upon whether there is a rational basis for harmonizing the two statutes.

In harmonizing Sections 315 and 315.4, we note that S.B. 1172 did not make any changes to Section 315, such as changing the term "shall" to "may" in subdivision (c) of Section 315 or deleting any subdivisions of Section 315. S.B. 1172 did not diminish the scope of the authority provided to the committee to adopt the uniform standards. In fact, the analysis of the Senate Committee on Business, Professions and Economic Development for S.B. 1172, dated April 19, 2010 (hereafter committee analysis), describes the purpose of S.B. 1172 and the enactment of Section 315.4, as follows:

"The Author points out that pursuant to SB 1441 (Ridley-Thomas, Chapter 548, Statutes of 2008), the DCA was required to adopt uniform guidelines on sixteen specific standards that would apply to substance abusing health care licensees, regardless of whether a board has a diversion program. Although most of the adopted guidelines do not need additional statutes for



implementation, there are a couple of changes that must be statutorily adopted to fully implement these standards. This bill seeks to provide the statutory authority to allow boards to order a licensee to cease practice if the licensee tests positive for any substance that is prohibited under the terms of the licensee's probation or diversion program, if a major violation is committed and while undergoing clinical diagnostic evaluation" (Committee analysis, at p. 4.)

The committee analysis further provides that the purpose of S.B. 1172 was to grant specific authority to implement those standards and "provide for the full implementation of the Uniform Standards" (committee analysis, at p. 11). The committee analysis at no time implies that the Legislature intended the Section 315 uniform standards to be revised or repealed by S.B. 1172 or that, in enacting Section 315.4, the Legislature intended that the implementation of the uniform standards be subject to the discretion of each healing arts board.

Thus, in our view, Section 315.4 may be reasonably construed in a manner that harmonizes it with Section 315. Specifically, we think that the intent of the Legislature in enacting Section 315.4 was not to make the uniform standards discretionary but to "provide for the full implementation of the Uniform Standards" by providing the authority to adopt regulations where the Legislature believed that further statutory authority was needed. Accordingly, we think implementation by the various healing arts boards of the uniform standards adopted under Section 315 is mandatory.<sup>4</sup>

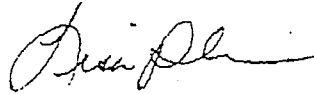
---

<sup>4</sup> Although Section 108 and Division 2 (commencing with Section 500) authorize the healing arts boards to set standards and adopt regulations (see, for example, Secs. 1224, 1614, 2018, 2531.95, 2615, 2715, 2854, 2930, 3025, 3510, and 3546), it is an axiom of statutory construction that a particular or specific provision takes precedence over a conflicting general provision (Sec. 1859, C.C.P.; *Agricultural Labor Relations Bd. v. Superior Court* (1976) 16 Cal.3d 392, 420, app. dism. *Kubo v. Agricultural Relations Bd.* (1976) 429 U.S. 802; see also Sec. 3534, Civ. C.). Thus, in our view, the specific requirement under Section 315 that the uniform standards be adopted supersedes any general provision authorizing the boards to set standards and adopt regulations.

Thus, it is our opinion that, if the uniform standards are properly adopted by the Substance Abuse Coordination Committee, the healing arts boards are required to implement them.

Very truly yours,

Diane F. Boyer-Vine  
Legislative Counsel



By  
Lisa M. Plummer  
Deputy Legislative Counsel

LMP:syl

**M e m o r a n d u m**

To : Doreathea Johnson  
Deputy Director & Chief Counsel  
Department of Consumer Affairs  
Legal Affairs Division

Date: February 29, 2012  
Telephone: (916) 445-7480  
FACSIMILE: (916) 324-8835  
E-mail: Kathleen.Lynch@doj.ca.gov

From : Kathleen A. Lynch  
Deputy Attorney General  
Government Law Section  
Office of the Attorney General – Sacramento

Subject : Uniform Standards Related to Substance-Abusing Licensees (Bus. & Prof. Code,  
§§ 315 - 315.4)

**Executive Summary**

Issues

You asked us to review Legislative Counsel's letter of October 27, 2011, which rendered certain opinions regarding the Substance Abuse Coordination Committee (SACC), which was created by Business and Professions Code section 315 to formulate uniform standards for use by the healing arts boards to deal with substance-abusing licensees. Legislative Counsel opined that:

- (1) SACC was required to formally promulgate the uniform standards as regulations pursuant to the Administrative Procedures Act (APA), and
- (2) the healing arts boards are required to use such standards under Business and Professions Code sections 315.

Summary of Responses

With respect to question (1), we see things differently from Legislative Counsel, in two respects.

First, we believe that SACC's adoption of uniform standards does not need to undergo the formal rule-making process under the APA. While other laws could potentially require the adoption of regulations when the standards are implemented by the boards (such as statutes governing particular boards or the APA's provisions applicable to disciplinary proceedings), we disagree that section 315 itself triggers the need to issue the uniform standards as regulations.

Second, even assuming the uniform standards must be adopted as regulations, we disagree with Legislative Counsel's apparent assumption that SACC would issue the regulations under section 315. The legislative histories of the relevant laws and statutory authorities of the

individual boards indicate that the boards would issue the regulations to implement the uniform standards.

As to question (2), we agree with Legislative Counsel that the healing arts boards must use the uniform standards under sections 315. A board cannot simply disregard a specific standard because it does not like the standard or because it believes that the standard is too cumbersome. However, some specific uniform standards themselves recognize a board's discretion whether to order a particular action in the first place. Thus, boards still retain authority to determine if they will undertake certain types of actions if permitted under a specific uniform standard.

### **Statutory Background**

In 2008, SACC was legislatively established within the Department of Consumer Affairs to create uniform standards to be used by the healing arts boards when addressing licensees with substance abuse problems. (Bus. & Prof. Code, § 315, subd. (a); Stats. 2008, ch. 548 (SB 1441).) By January 1, 2010, SACC was required to "formulate uniform and specific standards" in 16 identified areas "that each healing arts board shall use in dealing with substance-abusing licensees, whether or not a board chooses to have a formal diversion program." (*Id.* at § 315, subd. (c).) These 16 standards include requirements for: clinical diagnostic evaluation of licensees; the temporary removal of the licensee from practice for clinical diagnostic evaluation and any treatment, and criteria before being permitted to return to practice on a full-time or part-time basis; aspects of drug testing; whether inpatient, outpatient, or other type of treatment is necessary; worksite monitoring requirements and standards; consequences for major and minor violations; and criteria for a licensee to return to practice and petition for reinstatement of a full and unrestricted license. (*Ibid.*) SACC meetings to create these standards are subject to Bagley-Keene Act open meeting requirements. (*Id.* at subd. (b).)

On March 3, 2009, SACC conducted its first public hearing, which included a discussion of an overview of the diversion programs, the importance of addressing substance abuse issues for health care professionals, and the impact of allowing health care professionals who are impaired to continue to practice. (Sen. Com. on Business, Professions, and Economic Development, Analysis of SB 1172 (2010-2011 Reg. Sess.), as amended April 12, 2010.) During this meeting, SACC members agreed to draft uniform guidelines for each of the standards, and during subsequent meetings, roundtable discussions were held on the draft uniform standards, including public comments. (*Ibid.*) In December 2009, the Department of Consumer Affairs adopted the uniform guidelines for each of the standards required by SB 1441. (*Ibid.*) These standards have subsequently been amended by SACC, and the current standards were issued in April of 2011.

According to the author of SB 1441 (Ridley-Thomas), the intent of the legislation was to protect the public by ensuring that, at a minimum, a set of best practices or standards were adopted by health-care-related boards to deal with practitioners with alcohol or drug problems. (Assem. Com. on Business and Professions, Analysis of SB 1441 (2008-2009 Reg. Sess.), as amended June 16, 2008.) The legislation was also meant to ensure uniformity among the

standards established throughout the healing arts licensing boards under the Department of Consumer Affairs. (*Ibid.*) Specifically, the author explains:

SB 1441 is not attempting to dictate to [the health-related boards] how to run their diversion programs, but instead sets parameters for these boards. The following is true to all of these boards' diversion programs: licensees suffer from alcohol or drug abuse problems, there is a potential threat to allowing licensees with substance abuse problems to continue to practice, actual harm is possible and, sadly, has happened. The failures of the Medical Board of California's (MBC) diversion program prove that there must be consistency when dealing with drug or alcohol issues of licensees.

(Assem. Com. on Business and Professions, Analysis of SB 1441 (2008-2009 Reg. Sess.), as amended June 16, 2008.)

In the view of its author, "[t]his bill allows the boards to continue a measure of self-governance; the standards for dealing with substance-abusing licensees determined by the commission set a floor, and boards are permitted to establish regulations above these levels." (*Ibid.*)

In 2010, additional legislation was enacted to further implement section 315. Specifically, it provided that the healing arts boards, as described in section 315 and with the exception of the Board of Registered Nursing, "may adopt regulations authorizing the board to order a licensee on probation or in a diversion program to cease practice for major violations and when the board orders a licensee to undergo a clinical diagnostic evaluation pursuant to the uniform and specific standards adopted and authorized under Section 315." (Bus. & Prof. Code, § 315.4, subd. (a); Stats. 2010, ch. 517 (SB 1172).) An order to cease practice does not require a formal hearing and does not constitute a disciplinary action. (*Id.* § 315.4 subds. (b), (c).)

According to the author of SB 1172 (Negrete McLoud), this subsequent statute was necessary. "because current law does not give boards the authority to order a cease practice." (Sen. Com. on Business, Professions, and Economic Development, Analysis of SB 1172 (2010-2011 Reg. Sess.), as amended April 12, 2010.) The author explains:

Although most of the adopted guidelines do not need additional statutes for implementation, there are a few changes that must be statutorily adopted to fully implement these standards. [¶] This bill seeks to provide the statutory authority to allow boards to order a licensee to cease practice if the licensee tests positive for any substance that is prohibited under the terms of the licensee's probation or diversion program, if a major violation is committed and while undergoing clinical diagnostic evaluation. [¶] The ability of a board to order a licensee to cease practice under these circumstances provides a delicate balance to the inherent confidentiality of diversion programs. The protection of the public remains the top priority of boards when dealing with substance abusing licensees.

(Senate Third Reading, Analysis of SB 1172 (2010-2011 Reg. Sess.); as amended June 22, 2010.)

### Legal Analysis

**1a. Section 315 should be construed as not requiring that the uniform standards be adopted as regulations.**

Legislative Counsel opined that SACC must adopt the uniform standards as regulations under section 315, because (1) the standards meet the definition of regulations, (2) none of the express exemptions under Government Code section 11340.9 remove them from the APA rule-making process, and (3) section 315 contains no express language precluding application of the rulemaking provisions of the APA. (October 27, 2011 Letter, p. 5.) We have a different view on the threshold issue of whether the standards qualify as a regulation under section 315.

Under the APA, a regulation is defined as "every rule, regulation, order, or standard of general application or the amendment, supplement, or revision of any rule, regulation, order, or standard adopted by any state agency to implement, interpret, or make specific the law enforced or administered by it, or to govern its procedure." (Gov. Code, § 11342.600.) "No state agency shall issue, utilize, enforce, or attempt to enforce any guideline, criterion, bulletin, manual, instruction, order, standard of general application, or other rule, which is a regulation as defined in Section 11342.600, unless [it has been adopted in compliance with the APA]." (*Id.* § 11340.5, subd. (a).) This requirement cannot be superseded or modified by subsequent legislation, unless the statute does so expressly. (*Id.* § 11346, subd. (a).)

An agency standard subject to the APA has two identifying characteristics. First, the agency must intend its rule to apply generally, rather than in a specific case. Second, the rule must "implement, interpret, or make specific the law enforced or administered by [the agency], or . . . govern [the agency's] procedure." (*Morning Star Co. v. State Bd. of Equalization* (2006) 38

Cal.4th 324, 333, quoting *Tidewater Marine Western, Inc. et al. v. Bradshaw* (1996) 14 Cal.4th 557, 571.)

Whether a particular standard or rule is a regulation requiring APA compliance depends on the facts of each case, considering the rule in question, and the applicable statutory scheme. Generally speaking, courts tend to readily find the need for such compliance. We understand that certain healing arts boards have already adopted regulations incorporating the uniform standards. (See, e.g., Cal. Code Regs., tit. 16, § 4147 [Board of Occupational Therapy].) This approach is understandable in light of the usually broad requirement that agency rules be adopted as regulations and, as noted below, may be required by other laws when they are implemented by the boards. Here, however, the wording and intent of section 315 indicate the Legislature did not intend that the initial act of formulating and adopting the uniform standards is within the purview of the formal APA rule-making process.

“The fundamental rule of statutory construction is that the court should ascertain the intent of the Legislature so as to effectuate the purpose of the law.” (*Bodell Const. Co. v. Trustees of California State University* (1998) 62 Cal.App.4th 1508, 1515.) In determining that intent, courts “first examine the words of the statute itself. Under the so-called ‘plain meaning’ rule, courts seek to give the words employed by the Legislature their usual and ordinary meaning. If the language of the statute is clear and unambiguous, there is no need for construction. However, the ‘plain meaning’ rule does not prohibit a court from determining whether the literal meaning of a statute comports with its purpose. If the terms of the statute provide no definitive answer, then courts may resort to extrinsic sources, including the ostensible objects to be achieved and the legislative history.” (*Ibid.* [citations omitted].) Courts “must select the construction that comports most closely with the apparent intent of the Legislature, with a view to promoting rather than defeating the general purpose of the statute, and avoid an interpretation that would lead to absurd consequences.” (*Ibid.* [citation omitted].) “The legislative purpose will not be sacrificed to a literal construction of any part of the statute.” (*Ibid.*)

In *Paleski v. State Department of Health Services* (2006) 144 Cal.App.4th 713, the Court of Appeal applied these rules of statutory construction and found that the challenged agency criteria were not required to be adopted as regulations under the APA. (*Id.* at pp. 728-729.) In *Paleski*, plaintiff challenged an agency’s criteria for the prescription of certain drugs because the department had not promulgated them in compliance with the APA. (*Ibid.*) The statute, however, expressly authorized the criteria to be effectuated by publishing them in a manual. (*Ibid.*) According to the court, the “necessary effect” of this language was that the Legislature did not intend for the broader notice procedure of the APA to apply when the agency issued the criteria. (*Ibid.*)

Similar reasoning should apply here. Under the plain meaning of section 315, SACC was legislatively established to create uniform standards to be used by the healing arts boards when addressing licensees with substance abuse problems. (Bus. & Prof. Code, § 315, subd. (a).) The intent of the legislation was to protect the public and to ensure that minimum standards are met and to ensure uniformity among the standards established throughout the healing arts

licensing boards under the Department of Consumer affairs. (Assem. Com. on Business and Professions, Analysis of SB 1441 (2008-2009 Reg. Sess.), as amended June 16, 2008.) In formulating these uniform standards, SACC was subject to the Bagley-Keene Act, which requires noticed public meetings. Many roundtable discussions were held on the draft uniform standards, including public vetting and public comments. In that way, the affected community learned about the standards and had the opportunity to comment. This is a prime requirement and purpose of the APA rule-making process (see Gov. Code, § 11343 *et seq.*), but it has already been fulfilled by the procedures set forth in section 315. To now require SACC to repeat that process by promulgating the standards as regulations would make little sense and be duplicative.

Nor does the process for the formulation of the standards set forth in section 315 comport with the other purposes and procedures of the APA. During the APA rule-making process, an agency must provide various reasons, justifications, analyses, and supporting evidence for the proposed regulation. (Gov. Code, § 11346.2.) Those provisions and other provisions of the APA are intended to address the proliferation, content, and effect of regulations proposed by administrative agencies. (*Id.* §§ 11340, 11340.1.) Here, the agency is not proposing to adopt the uniform standards. The Legislature has required that the standards adopted by SACC, be uniform, and be used by the boards. Given this statutory mandate that they be implemented, subjecting the uniform standards to substantive review under the APA again makes little sense.<sup>1</sup>

**1b. The SACC would not be the rule-making entity, even if the uniform standards would have to be adopted as regulations.**

Even assuming that APA compliance was required under section 315, it is doubtful that SACC would carry the responsibility to adopt regulations. The second component of a regulation requires that the rule must “implement, interpret, or make specific the law enforced or administered by [the agency], or . . . govern [the agency’s] procedure.” (*Morning Star Co.*, *supra*, 38 Cal.4th at p. 333.) Here, SACC was mandated to create the uniform standards to be used by separate boards; the SACC’s creation of the uniform standards does not implement,

---

<sup>1</sup> Even though the standards do not have to be promulgated as regulations by SACC under section 315, this does not mean that certain regulations would not arguably be required on the part of some or all of the boards under other statutory schemes, such as the laws applicable to a particular board or the APA’s provisions on quasi-adjudicatory proceedings. This type of analysis would require a fact specific, case-by-case study of each board’s practices and its regulatory scheme and may include consideration of: (1) whether a board’s statutory authority requires the adoption of regulations related to actions against substance-abusing licensees, (2) whether current regulations conflict with the standards, and (3) whether in an administrative adjudicative setting, the standards are considered “penalties” and thus must be adopted as regulations under section 11425.50, subdivision (e), of the Government Code.



interpret, or make any law more specific. (Bus. & Prof. Code, § 315, subds. (a), (c).) The only express statutory role of the SACC is to determine the uniform standards in the first place.<sup>2</sup>

The boards are then required to use and apply the standards and have much clearer authority to adopt regulations. "Each of the boards [within the Department of Consumer Affairs] exists as a separate unit, and has the function of setting standards, holding meetings, and setting dates thereof, preparing and conducting examinations, passing upon applicants, conducting investigations of violations of laws under its jurisdiction, issuing citations and hold hearings for the revocation of licenses, and the imposing of penalties following such hearings, in so far as these powers are given by statute to each respective board." (Bus. & Prof. Code, § 108.)

The legislative history for section 315 also supports this conclusion. According to its author, section 315 was adopted to protect the public by ensuring that, at a minimum, a set of best practices or standards *were adopted by health care related boards to deal with practitioners with alcohol or drug problems*. (Assem. Com. on Business and Professions, Analysis of SB 1441 (2008-2009 Reg. Sess.), as amended June 16, 2008, emphasis added.)<sup>3</sup> Practically speaking, it would be difficult for the SACC (or the Department of Consumer Affairs) to draft regulations applicable to all boards, given that they are unique and deal with different subject areas, unless such regulations were adopted wholesale, on a one-size-fits-all basis. As explained below, while the healing arts boards must use the standards, they only have to use the ones that apply to their procedures.

Thus, while section 315 does not require regulations to initially adopt the standards, the boards (and not SACC) would more reasonably be tasked with this responsibility.

**2. The healing arts boards must use the uniform standards to the extent that they apply.**

The original language of section 315 is clear that the standards must be used. (Bus. & Prof. Code, § 315, subd. (a) ["uniform standards that will be used by healing arts boards"], subd. (b) ["uniform standards . . . that each healing arts board shall use in dealing with substance-abusing licenses"].) Legislative Counsel was asked to opine on whether subsequent legislation (Bus. & Prof. Code, § 315.4) somehow made these uniform standards discretionary. We agree with

---

<sup>2</sup> The SACC is a committee formed by various executive officers of healing arts boards and other public officials formed within the Department of Consumer Affairs. (Bus. & Prof. Code, § 315, subds. (a).)

<sup>3</sup> As discussed shortly, the legislative history for follow-up legislation similarly explains that its purpose was to provide statutory authority for some healing arts boards to issue regulations to implement certain of the uniform standards. (Sen. Com. on Business, Professions, and Economic Development, Analysis of SB 1172 (2010-2011 Reg. Sess.), as amended April 12, 2010.)

Legislative Counsel's conclusion that section 315.4 did not make the uniform standards optional. (Oct. 27, 2011, Letter, p. 9.)

Section 315.4 was enacted two years after section 315, and provides that that the healing arts boards, as described in section 315 and with the exception of the Board of Registered Nursing, "may adopt regulations authorizing the board to order a licensee on probation or in a diversion program to cease practice for major violations and when the board orders a licensee to undergo a clinical diagnostic evaluation pursuant to the uniform and specific standards adopted and authorized under Section 315." (Bus. & Prof. Code, § 315.4, subd. (a); Stats. 2010, ch. 517, (SB 1172).) If a board adopts such regulations, there is nothing to indicate that use of uniform standards created under section 315 is optional. Such an interpretation would be contrary to the legislative intent. Section 314.5 was enacted for the limited purpose to give boards the authority to order a licensee to cease practice, as this was not provided for in section 315. (Sen. Com. on Business, Professions, and Economic Development, Analysis of SB 1172 (2010-2011 Reg. Sess.), as amended April 12, 2010.) By no means was the intent to transform the mandatory uniform standards of section 315 into optional suggestions. As the author explains:

Although most of the adopted guidelines do not need additional statutes for implementation, there are a few changes that must be statutorily adopted to fully implement these standards. [¶] This bill seeks to provide the statutory authority to allow boards to order a licensee to cease practice if the licensee tests positive for any substance that is prohibited under the terms of the licensee's probation or diversion program, if a major violation is committed and while undergoing clinical diagnostic evaluation.

(Senate Third Reading, Analysis of SB 1172 (2010-2011 Reg. Sess.), as amended June 22, 2010.)

In addition, some specific uniform standards themselves recognize a board's discretion whether to order a particular action in the first place. (See e.g. Uniform Standard # 1 ["If a healing arts board orders a licensee . . . to undergo a clinical diagnosis evaluation, the following applies: . . ."].) The standards must be applied, however, if a board undertakes a particular practice or orders an action covered by the standards. A determination regarding a board's specific application (or not) of certain uniform standards would have to be based on a fact specific, case-by-case review of each board and its regulatory scheme. However, once a board implements a procedure covered by the uniform standards, it cannot disregard the applicable uniform standard because it disagrees with the standard's substance.

### Conclusion

For the reasons stated above, in our view, section 315 can be read to preclude the necessity to adopt regulations when the uniform standards are issued initially. And even if regulations were required under section 315, SACC would not be tasked with this responsibility. We also

Doreatha Johnson

February 29, 2012

Page 9

believe that the healing arts boards must use the uniform standards where an agency undertakes an action covered by the standards.

Please feel free to contact me if you have any questions or would like to discuss the above.

:KAL

cc: Peter K. Southworth, Supervising Deputy Attorney General

# Attachment 3

## Title 16. Board of Pharmacy Proposed Language

To Amend § 1746 in Article 5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

### § 1746. Emergency Contraception

(a) A pharmacist furnishing emergency contraception pursuant to Section ~~4052(a)(8)~~ 4052.3(a)(2) of the Business and Professions Code shall follow the protocol specified in subdivision (b) of this section.

(b) Protocol for Pharmacists Furnishing Emergency Contraception (EC).

~~(1) Authority: Section 4052 of the California Business and Professions Code authorizes a pharmacist to furnish emergency contraception pursuant to the protocols specified in Business and Professions Code section 4052.3. Use of the following protocol satisfies that requirement.~~

(1) Authority: Section 4052.3(a)(2) of the California Business and Professions Code authorizes a pharmacist to furnish emergency contraception pursuant to a protocol approved by the California State Board of Pharmacy and the Medical Board of California. Use of the protocol specified in this section satisfies that requirement.

(2) Purpose: To provide timely access to emergency contraceptive medication ~~within required limits~~ and ensure that the patient receives adequate information to successfully complete therapy.

(3) Procedure: When a patient requests emergency contraception, the pharmacist will ask and ~~state~~ communicate the following:

Are you allergic to any medications?

Timing is an essential element of the product's effectiveness. EC should be taken as soon as possible after unprotected intercourse. Treatment may be initiated up to five days (120 hours) ~~of after~~ after unprotected intercourse. ~~EC effectiveness declines gradually over five days and EC use will not interfere with an established pregnancy.~~

EC use will not interfere with an established or implanted pregnancy.

If more than 72 hours have elapsed since unprotected intercourse, the use of ella™ (ulipristal) may be more effective than levonorgestrel. Other options for EC include consultation with your physician regarding insertion of an IUD.

(4) The pharmacist shall provide ~~the~~ a fact sheet and review any questions the patient may have regarding EC. In addition, the pharmacist shall collect the information required for a

patient medication record required by Section 1707.1 of Title 16 of the California Code of Regulations.

Fact Sheet: The pharmacist will provide the patient with a copy of the current EC fact sheet approved by the Board of Pharmacy as required by Business and Professions Code Section ~~4052(b)(3)~~ 4052.3(e).

(5) Referrals and Supplies: If emergency contraception services are not immediately available at the pharmacy or the pharmacist declines to furnish pursuant to conscience clause, the pharmacist will refer the patient to another emergency contraception provider. The pharmacist shall comply with all state mandatory reporting laws, including sexual abuse laws.

(6) The pharmacist may provide up to 12 non-spermicidal condoms to each Medi-Cal and Family PACT client who obtains emergency contraception.

(7) Advanced provision: The pharmacist may dispense emergency contraception medication for a patient in advance of the need for emergency contraception.

(8) EC Product Selection: The pharmacist will provide emergency contraception medication ~~compatible with product information~~ from the list of products specified in this protocol. This list must be kept current and maintained in the pharmacy. Along with emergency contraception products, the list will include adjunctive medications indicated for nausea and vomiting associated with taking EC containing estrogen. Patients will be provided information concerning dosing and potential adverse effects.

(9) Documentation: Each prescription authorized by a pharmacist will be documented in a patient medication record as required by law.

(10) Training: Prior to furnishing emergency contraception, pharmacists who participate in ~~the~~ this protocol must have completed a minimum of one hour of continuing education specific to emergency contraception.

~~(11) Brands and Doses of Oral Contraceptive Tablets Used for Emergency Contraception.~~

(11) Brands and Doses of Oral Contraceptive Tablets Used for Emergency Contraception.

**Dedicated Emergency Contraception**

Brand	Manufacturer	Tablets per Dose	Ethinyl Estradiol per Dose (mg)	Levonorgestrel per Dose (mg)**
<b>One-Dose Regimen</b>				
Plan-B	Women's Capital Corporation	2 tablets	0	1.5
<b>Two-Dose Regimens</b>				
Plan-B	Women's Capital Corporation	1 tablet per dose	0	0.75
Preven	Gynetics	2 tablets per dose	100	0.50
<b>Oral Contraceptive Pills</b>				
Brand	Manufacturer	Tablets per Dose (two doses 12 hours apart*)	Ethinyl Estradiol per Dose (mg)	Levonorgestrel per Dose (mg)**
Levora	Watson	4 white tablets	120	0.60
Ovral	Wyeth	2 white tablets	100	0.50
Ogestrel	Watson	2 white tablets	100	0.50
Nordette	Wyeth	4 light-orange tablets	120	0.60
Tri-Levlen	Berlex	4 yellow tablets	100	0.50
Alesse	Wyeth	5 pink tablets	100	0.50
Aviane	Duramed	5 orange tablets	100	0.50
Triphasil	Wyeth	4 yellow tablets	120	0.50
Levlen	Berlex	4 light-orange tablets	120	0.60
Trivora	Watson	4 pink tablets	120	0.50
Levlite	Berlex	5 pink tablets	100	0.50
Lo/Ovral	Wyeth	4 white tablets	120	0.60
Low-Ogestrel	Watson	4 white tablets	120	0.60
Ovrette	Wyeth	20 yellow tablets	0	0.75

\* The progestin in Ovral, Lo/Ovral, and Ovrette is norgestrel, which contains two isomers, only one of which (levonorgestrel) is bioactive; the amount of norgestrel in each dose is twice the amount of levonorgestrel

(11) Medications Used for Emergency Contraception

<b><u>Dedicated Approved Products for Emergency Contraception</u></b>			
<u>Brand</u>	<u>Dose</u>	<u>Ethinyl Estradiol per dose (mcg)</u>	
<b><u>One Dose Regimen</u></b>			
<u>Plan B™ One-Step</u>	<u>1 tablet</u>	<u>0</u>	<u>1.5mg levonorgestrel</u>
<u>ella™</u>	<u>1 tablet</u>	<u>0</u>	<u>30mg ulipristal</u>
<b><u>Two Dose Regimen</u></b>			
<u>Next Choice™</u>	<u>1 tablet per dose</u>	<u>0</u>	<u>1.5mg levonorgestrel</u>
<b><u>Oral Contraceptive Pills</u></b>			
<u>Brand</u>	<u>Tablets per Dose (two doses 12 hours apart*)</u>	<u>Ethinyl Estradiol per dose (mcg)</u>	<u>Levonorgestrel per dose (mg)*</u>
<u>Allesse</u>	<u>5 pink tablets</u>	<u>100</u>	<u>0.50</u>
<u>Aviane</u>	<u>5 orange tablets</u>	<u>100</u>	<u>0.50</u>
<u>Levlen</u>	<u>4 light-orange tablets</u>	<u>120</u>	<u>0.60</u>
<u>Levlite</u>	<u>5 pink tablets</u>	<u>100</u>	<u>0.50</u>
<u>Levora</u>	<u>4 white tablets</u>	<u>120</u>	<u>0.60</u>
<u>Lo/Ovral</u>	<u>4 white tablets</u>	<u>120</u>	<u>0.50</u>
<u>Low-Ogestrel</u>	<u>4 white tablets</u>	<u>120</u>	<u>0.60</u>
<u>Nordette</u>	<u>4 light-orange tablets</u>	<u>120</u>	<u>0.60</u>
<u>Ogestrel</u>	<u>2 white tablets</u>	<u>100</u>	<u>0.50</u>
<u>Ovral</u>	<u>2 white tablets</u>	<u>100</u>	<u>0.50</u>
<u>Tri-Levlen</u>	<u>4 yellow tablets</u>	<u>100</u>	<u>0.50</u>
<u>Triphasil</u>	<u>4 yellow tablets</u>	<u>120</u>	<u>0.50</u>
<u>Trivora</u>	<u>4 pink tablets</u>	<u>120</u>	<u>0.50</u>
<u>Ovrette</u>	<u>20 yellow tablets</u>	<u>0</u>	<u>0.75</u>

\*The progestin in Ovral, Lo/Ovral, and Ovrette is norgestrel, which contains two isomers, only one of which (levonorgestrel) is bioactive; the amount of norgestrel in each dose is twice the amount of levonorgestrel.

In addition to the products specified in this paragraph, generic equivalent products may be furnished. Estrogen containing regimens are not preferred and should be used only when the other options are not available.



(12) Anti-nausea Treatment Options for use with Emergency Contraception

<b><u>Anti-Nausea Treatment Options For Use With Emergency Contraception</u></b>		
<b>Drug</b>	<b>Dose</b>	<b>Timing of Administration</b>
<b>Non-prescription Drugs</b>		
Meclizine hydrochloride (Dramamine II, Bonine)	One or two 25 mg tablets	1 hour before first EC dose; Repeat if needed in 24 hours
Diphenhydramine hydrochloride (Benadryl)	One or two 25 mg tablets or capsules.	1 hour before first EC dose; repeat as needed every 4-6 hours
Dimenhydrinate (Dramamine)	One or two 50 mg tablets or 4-8 teaspoons liquid	30 minutes to 1 hour before first <del>ECP</del> <u>EC</u> dose; repeat as needed every 4-6 hours
Cyclizine hydrochloride (Marezine)	One 50 mg tablet	30 minutes before first EC dose; repeat as needed every 4-6 hours

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4052 and 4052.3, Business and Professions Code. Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4052 and 4052.3, Business and Professions Code.

Amanda Davis, Pharm.D.  
10972 Campus Street  
Loma Linda, CA 92354

February 16, 2012

California Board of Pharmacy  
1625 North Market Boulevard, N219  
Sacramento, CA 95834

To Carolyn Klein and the Board of Pharmacy:

I am writing in regards to the proposed amendment to § 1746 of Article 5 of Division 17 of Title 16 of the California Code of Regulations regarding emergency contraception, specifically, subdivision (b)(3). There are several erroneous, unclear, and problematic statements that I believe must be addressed before this amendment is to take effect.

First, with the advent of ulipristal acetate on the market as an alternative emergency contraceptive, it is important to differentiate between the two types of emergency contraception when counseling patients. Although they are used for the same purpose, they have very different properties. Because of this, I suggest that you strike the phrase "EC use will not interfere with an established or implanted pregnancy." and replace it with, "Progesterone-based emergency contraception will not interfere with an established pregnancy," or any similar phrase that would exclude ulipristal. Considering the current scientific evidence regarding ulipristal, it would be incorrect tell a patient, implicitly or explicitly, that this medication cannot disrupt an established pregnancy. Such evidences can be found in animal studies on guinea pigs (1), rats (2), and macaque monkeys (3) where ulipristal acetate was found to be capable of inducing abortion. Human studies have found that the corpus luteum, which is necessary for maintaining pregnancy in early gestation, can undergo luteolysis after doses as low as 1 mg of ulipristal acetate are taken (4). Additionally, the official assessment report published by the European Medicines Agency for ellaOne (the trade name for ella in Europe) states that, "Ulipristal acetate prevents progesterone from occupying its receptor, thus the gene transcription normally turned on by progesterone is blocked, and the proteins necessary to begin **and maintain** pregnancy are not synthesized" (5). It is for these reasons that I recommend that the statement be changed from a blanket statement concerning all emergency contraception to a more directed statement concerning only progesterone-based emergency contraceptives. This is something that might also be applied to the EC fact sheet for patients.

Second, I would like to suggest that you strike the point, "If more than 72 hours have elapsed since unprotected intercourse, the use of ella™ (ulipristal) may be more effective than levonorgestrel. Other options for EC include consultation with your physician regarding insertion of an IUD." and replacing it with the phrase, "If more than 72 hours have elapsed since unprotected intercourse, consult with your physician to discuss other options for EC." There are three reasons why the current phrasing is problematic:

1. Ulipristal is only approved for EC up to 120 hours post unprotected intercourse; therefore, recommending the use of ulipristal “more than 72 hours” after intercourse would only be accurate if less than 120 hours has elapsed since the event. The proposed phrasing does not specify this and may provide confusing or inaccurate information to the patient.
2. If more than 72 hours have elapsed since unprotected intercourse, whether it be 5 days or 10 days, the ONLY other option a patient has is to consult with their doctor. We cannot provide ella at the pharmacy without a prescription, so it would be more beneficial to recommend that they see their physician immediately.
3. Since ulipristal has abortifacient properties and is likely able to cause a drug-induced abortion in the early stages of gestation, the recommendation of this particular product to patients is morally problematic. Like levonorgestrel, ulipristal is capable of preventing pregnancy, and if this was its only mechanism of action, then it might be appropriate to recommend this product in the pharmacy; however, given the abortifacient nature of this drug, we should be weary to casually recommend this medication to patients without even counseling them on its mechanism of action or even ascertaining their views on abortion. The pharmacy is no place to impose such a grave and life-altering decision on women. The California medical board and board of pharmacy should reconsider standing behind this drug when many of the pharmacists in this state do not stand behind it at all.

Thank you for taking the time to read through and consider my comments on this amendment. My hope and goal is for women to receive informed and accurate information from their pharmacists on emergency contraception and for pharmacists to feel confident in the medications that they are recommending to their patients.

Sincerely,

Amanda Davis, Pharm.D.

## References

1. Poyser NL, Forcelledo ML. A comparison of the pregnancy-terminating potencies of three anti-progestins in guinea-pigs, and the effects of sulprostone. *Prostaglandins Leukotrienes and Essential Fatty Acids* (1994) 50; 245-247.
2. Teutsch G, Philibert D. History and perspectives of antiprogestins from the chemist's point of view. *Hum Reprod.* 1994 Jun;9 Suppl 1:12-31.
3. Tarantal AF, Hendrickx AG, Matlin SA, et al. Effects of two anti-progestins on Early Pregnancy in the long-tailed macaque. *Contraception.* 1996;54:107-115.
4. Passaro MD, *et al.* Luteal phase dose-response relationships of the antiprogestin CDB-2914 in normally cycling women. *Human Reproduction.* 2003; 18(9): 1820-1827.
5. CHP Assessment Report for ellaOne. European Medicines Agency: *Evaluation of Medicines for Human Use.* Doc.Ref.: EMEA/261787/2009.

Follow up  
 You replied on 1/23/2012 7:33 AM.  
 This message was sent with High importance.

From: Kathy Besinque [kbesin@pharmacy.usc.edu]

Sent: Fri 1/13/2012 3:27 PM

To: Klein, Carolyn@DCA

Cc:

Subject: EC Language

There is one error in the posting of the EC language and one addition (see below)-

<b><u>Dedicated Approved Products for Emergency Contraception</u></b>			
<u>Brand</u>	<u>Dose</u>	<u>Ethinyl Estradiol per dose (mcg)</u>	
<b><u>One Dose Regimen</u></b>			
<u>Plan B™ One-Step</u>	<u>1 tablet</u>	<u>0</u>	<u>1.5mg levonorgestrel</u>
<u>ella™</u>	<u>1 tablet</u>	<u>0</u>	<u>30mg ulipristal</u>
<b><u>Two Dose Regimen</u></b>			
<u>Next Choice™</u>	<u>1 tablet per dose</u>	<u>0</u>	<u>Each tablet is 0.75mg</u>

Note- Levonorgestrel tablets are new – it is a generic that uses  
 Thank you

Kathleen Hill-Besinque, Pharm.D., MEd., FASHP, FCSHP  
 Assistant Dean, Curriculum and Assessment  
 Director, Professional Experience Programs  
 USC School of Pharmacy  
 1985 Zonal Avenue Suite 200C  
 Los Angeles, CA 90089  
 kbesin@usc.edu

**Dedicated Approved Products for Emergency Contraception**

Brand

Dose Ethinyl Estradiol per dose (mcg)

One Dose Regimen

Plan B™ One-Step

1 tablet

0 1.5mg

levonorgestrel

ella™ 1 tablet 0 30mg ulipristal

Two Dose Regimen

Next Choice™

Levonorgestrel Tablets

1 tablet per dose

0 Each tablet is 0.75mg levonorgestrel

# Attachment 4

## Title 16. Board of Pharmacy Proposed Language

**To Add Section 1762 to Article 8 of Division 17 of Title 16 of the California Code of Regulations to read as follows:**

### **§ 1762. Unprofessional Conduct Defined.**

In addition to those acts detailed in Business and Professions Code Section 4301, the following shall also constitute unprofessional conduct:

(a) Including or permitting to be included any of the following provisions in an agreement to settle a civil dispute arising from the licensee's practice, whether the agreement is made before or after the filing of an action:

(1) A provision that prohibits another party to the dispute from contacting, cooperating, or filing a complaint with the board; or,

(2) A provision that requires another party to the dispute to attempt to withdraw a complaint the party has filed with the board.

(b) Failure without lawful excuse to provide records requested by the board within 15 days of the date of receipt of the request or within the time specified in the request, whichever is later.

(c) Failure or refusal to comply with any court order issued in the enforcement of a subpoena, mandating the release of records to the board.

(d) Commission of any act resulting in the requirement that a licensee or applicant registers as a sex offender. The board may revoke the license of any licensee and deny the application of any applicant who is required to register as a sex offender pursuant to Section 290 of the Penal Code or any other equivalent federal, state or territory's law that requires registration as a sex offender.

Authority: Section 4005, Business and Professions Code. Reference: Sections 726, 4300 and 4301, Business and Professions Code.

## Title 16. Board of Pharmacy Proposed Language

**To Amend § 1769 in Article 8 of Division 17 of Title 16 of the California Code of Regulations to read as follows:**

### **§ 1769. Criteria for Rehabilitation.**

(a) In addition to any other requirements for licensure, when considering the approval of an application, the board or its designee may require an applicant to be examined by one or more physicians and surgeons or psychologists designated by the board if it appears that the applicant may be unable to safely practice due to mental illness or physical illness affecting competency. An applicant's failure to comply with the examination requirement shall render his or her application incomplete. The board shall pay the full cost of such examination. The board shall seek that the evaluation be conducted within 60 days of the date the applicant is advised that an examination is required. The board shall receive the examiner's evaluation within 60 days of the date the examination is completed. The report of the examiner shall be made available to the applicant.

If after receiving the report of the evaluation, the board determines that the applicant is unable to safely practice, the board may deny the application.

~~(a)~~ (b) When considering the denial of a facility or personal license under Section 480 of the Business and Professions Code, the board, in evaluating the rehabilitation of the applicant and his present eligibility for licensing or registration, will consider the following criteria:

- (1) The nature and severity of the act(s) or offense(s) under consideration as grounds for denial.
- (2) Evidence of any act(s) committed subsequent to the act(s) or crime(s) under consideration as grounds for denial under Section 480 of the Business and Professions Code.
- (3) The time that has elapsed since commission of the act(s) or crime(s) referred to in subdivision (1) or (2).
- (4) Whether the applicant has complied with any terms of parole, probation, restitution or any other sanctions lawfully imposed against the applicant.
- (5) Evidence, if any, of rehabilitation submitted by the applicant.

~~(b)~~ (c) When considering the suspension or revocation of a facility or a personal license on the ground that the licensee or the registrant has been convicted of a crime, the board, in evaluating the rehabilitation of such person and his present eligibility for a license will consider the following criteria:



(1) Nature and severity of the act(s) or offense(s).

(2) Total criminal record.

(3) The time that has elapsed since commission of the act(s) or offense(s).

(4) Whether the licensee has complied with all terms of parole, probation, restitution or any other sanctions lawfully imposed against the licensee.

(5) Evidence, if any, of rehabilitation submitted by the licensee.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4030, 4200 and 4400, Business and Professions Code.